

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

SAN ROCCO THERAPEUTICS, LLC,

Plaintiff,

v.

NICK LESCHLY, MITCHELL FINER, PHILIP REILLY, CRAIG THOMPSON, THIRD ROCK VENTURES, LLC, BLUEBIRD BIO, INC, 2SEVENTY BIO, INC,

Defendants.

Civil Action No. 1:23-cv-10919

Leave to file granted on September 20, 2023
[ECF 59]

**PLAINTIFF SAN ROCCO THERAPEUTIC, LLC'S BRIEF IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT**

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Plaintiff San Rocco Therapeutics, LLC (“Plaintiff” or “SRT”) hereby opposes Defendants Nick Leschly, Mitchell Finer, Philip Reilly, Third Rock Ventures, LLC, bluebird bio, Inc, and 2seventy bio, Inc.’s (collectively “Defendants” or the “Non-Thompson Defendants”) Motion to Dismiss (ECF 56) SRT’s August 7, 2023 First Amended Complaint (“FAC”) (ECF 42).

INTRODUCTION

“On a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must accept as true all well-pleaded facts, analyze those facts in the light most hospitable to the plaintiff’s theory, and draw all reasonable inferences from those facts in favor of the plaintiff.” *Picone v. Shire PLC*, No. 16-CV-12396-ADB, 2017 WL 4873506, at *4 (D. Mass. Oct. 20, 2017) (citing *US ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F. 3d 377, 383–84 (1st Cir. 2011)). “To avoid dismissal, a complaint must set forth,” like the FAC does here, “factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory.” *Id.* (citing *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008)). For the reasons discussed herein, the Court should deny Defendants’ motion to dismiss Counts I–XIV.

As an initial matter, Defendants’ statement that SRT’s FAC is a “misuse of the judicial system in pursuit of a personal vendetta[,]” ECF 57 at 12, and citation to a quote taken from Authority Magazine, *id.* at 12 n.1, are improper and not relevant to their Motion to Dismiss. Defendants’ tactics lack civility.¹ The Court should disregard Defendants’ improper rhetoric. The

¹ This is not the first time that Defendants’ actions have lacked civility. In May 2022, during a conference about the Authority Magazine publication, counsel for Defendants were made aware about “comments made by bluebird’s executives directed to potentially harm Mr. Girondi, which he perceived as threatening. And, [s]hould defendants [bluebird and Third Rock] engage in any conduct that reasonably appears to be threatening to Mr. Girondi or his family, they may reserve the right to seek assistance from the proper authorities.” Ex. 1, 2. Indeed, Defendants edited the Authority Magazine quote to omit “[m]y son would have been cured by now if it was not for their

detailed FAC, which is 590 paragraphs, more than adequately states a plausible claim for all counts.

I. DEFENDANTS' MOTION TO DISMISS THE RICO CLAIMS SHOULD BE DENIED

“To state a claim for any RICO offense, a plaintiff must sufficiently allege: “(1) the conduct (2) of an enterprise (3) through a pattern of racketeering activity.” *United States v. Velazquez-Fontanez*, 6 F.4th 205, 212 (1st Cir. 2021) (internal citations and quotation marks omitted). A plaintiff must also establish that the defendants’ RICO actions caused it injury. *Efron v. Embassy Suites (P.R.), Inc.*, 223 F.3d 12, 17 (1st Cir. 2000).² SRT adequately alleges plausible RICO claims pursuant to 18 U.S.C. § 1962(c), (a), (b), and (d).

A. Each RICO Count Falls Within The Statute of Limitations

Contrary to Defendants’ arguments, ECF 57 at 18–20, SRT’s RICO claims are not time-barred. Defendants’ acts forming SRT’s RICO claims include, *inter alia*, fraudulent inducement of SRT in connection with a November 2, 2020 Settlement Agreement (“Settlement Agreement”), their fraudulent spinoff of 2seventy bio (“2seventy”), and their conspiracy to make materially false statements to the FDA about SRT’s drug product, FAC, ¶¶ 1, 17, 22, 27—all of which occurred *after* November 2, 2020, well-within the four year statute of limitations. *In re Lupron Marketing*

greed and actions” and [bluebird and Third Rock’s actions have] “cost many lives, many years of life.” *Id.*, 4. Defendants’ actions to delay SRT’s life saving treatment through sabotage and fraud so that Defendants could launch first for financial gain resulted in a life-saving drug being substantially delayed and costing children’s lives. Defendants further omitted the conclusion of this discussion, including tolerance and trying to see the good in people. Defendants resort to these personal attacks on the family of SRT’s CEO because they cannot confront the merits of the FAC, as discussed herein.

² The effect on interstate and/or foreign commerce is also an element of any RICO claim, but Defendants do not (and *cannot*) contest that the FAC sufficiently alleges interstate and/or foreign commerce. Defendants further concede that they formed an enterprise.

& Sales Practices Litig., 295 F. Supp.2d 148, 183 (D. Mass. 2003) (citing *Agency Holding Corp. v. Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 156 (1987)).

Even if one of Defendants' predicate acts occurred more than four years before SRT's lawsuit, each of SRT's RICO claims are nonetheless timely. While the statute of limitations for a civil RICO claim ordinarily "begins to run at the time the plaintiff knew or should have known of the injury[,]” “[t]he federal doctrine of fraudulent concealment operates to toll the statute of limitations where a plaintiff has been injured by fraud and remains in ignorance of it without any fault or want of diligence or care on his part.” *In re Lupron*, 295 F. Supp.2d at 183 (citing *Salois v. The Dime Savings Bank of N.Y.*, 128 F.3d 20 (1st Cir. 1997)). “To invoke the doctrine of fraudulent concealment, a plaintiff must plead and prove three elements: (1) wrongful concealment of their actions by the defendants; (2) failure of the plaintiff to discover the operative facts that are the basis of the cause of action within the limitations period; and (3) plaintiff’s due diligence until discovery of the facts.” *Id.*, (quoting *Berkson v. Del Monte Corp.*, 743 F.2d 53, 55 (1st Cir. 1984)). “Whether a plaintiff knew or should have known of an injury so as to trigger the running of a statute of limitations is, with rare exception, *a jury issue*.” *Id.* at 183–84 (emphasis added). This is exactly what SRT alleges occurred here.

As detailed in the FAC, on October 21, 2021, Defendants' fraudulent inducement was first exposed in 2022 during SRT's patent infringement litigation filed in Delaware, FAC, ¶¶ 223–49, which is a cause of action that could not accrue until *after* November 2, 2020, when SRT was granted an exclusive (worldwide) license to the asserted patents under the Settlement Agreement. Defendants claim that “the alleged RICO violations accrued no later than 2017, six years ago, when SRT filed the New York Litigation[.]” ECF 57 at 19. Thus, according to Defendants, the conspiracy alleged in the New York Litigation “is the same conspiracy alleged here[,]” despite the

fact that the Settlement Agreement was not in effect at the time (and 2seventy did not yet exist). *Id.* Defendants' arguments are fatally flawed. The Supreme Court has made clear that "a new predicate act can be used to obtain recovery for injuries related to the new predicate acts." *Lawson v. FMR, LLC*, 554 F. Supp.3d 186, 194 (D. Mass. 2021) (citing *Rotella v. Wood*, 528 U.S. 549, 558 (2000), and *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 190 (1997)). The new predicate acts committed by Defendants include, *inter alia*, Defendants' fraudulent inducement of SRT in connection with the Settlement Agreement, their fraudulent spinoff of 2seventy, and their conspiracy to make materially false statements about SRT's drug product to the FDA in violation of 18 U.S.C. § 1001, all of which occurred after November 2, 2020. FAC, ¶¶ 1, 17, 22, 27. Each of these predicate acts have caused new and separately distinct injuries against SRT. *Id.*, ¶¶ 17, 21. And, each new injury is entirely distinct from the other prior injuries that SRT suffered as a result of Defendants' previous acts. For example, SRT's new injuries involve significant financial losses due to filing fees, litigation costs, attorneys' fees SRT was forced to incur in response to Defendants' IPR petitions, *see id.*, ¶¶ 325–26, 566; the dismissal of the Massachusetts Litigation, with prejudice, where damages were in excess of 100 million dollars, *id.*, ¶ 324; and the substantial delay of entry of their TNS9 drug product into the market, *id.*, ¶ 322.

B. SRT Has Adequately Alleged All Of The Elements Required to Satisfy Each Federal RICO Claim

SRT has sufficiently alleged that each Defendant has committed the requisite conduct and/or predicate acts constituting "racketeering activity." Under the Federal RICO statute, conduct is defined as a "predicate act" constituting "racketeering activity[,] which includes "any act indictable under one of numerous federal criminal provisions" defined within the Federal RICO statute. *Fleet Credit Corp. v. Sion*, 893 F.2d 441, 444 (1990). As relevant here, such indictable offenses include 18 U.S.C. § 1341 (committing mail fraud) and 18 U.S.C. § 1343 (committing

wire fraud). 18 U.S.C. § 1962(1)(B). Criminal mail and wire fraud involves (1) a scheme based on an intent to defraud and (2) the use of mails or wire to further that scheme. *In re Lupron*, 295 F. Supp.2d at 165 (citing *Neder v. United States*, 57 U.S. 1, 20 (1999)). “The in furtherance requirement is to be read broadly.” *United States v. Simon*, 12 F.4th 1, 33 (1st Cir. 2021). SRT need not show that the mail or wire communications actually contain the fraudulent misrepresentation, only “that the mailing was incident to an essential part of the scheme.” *Id.* And, “[n]othing in the mail and wire fraud statutes requires that the party deprived of money or property be the same party who is actually deceived.” *AngioDynamics, Inc. v. Clarion Med. Techs.*, No. CV 18-30038-MGM, 2019 WL 10787926, at *14 (D. Mass. Sept. 25, 2019). While claims of mail and wire fraud must be pled with particularity pursuant to Federal Rule of Civil Procedure 9(b), *Giuliano v. Fulton*, 399 F.3d 381, 388 (1st Cir. 2005), “the First Circuit has concluded that courts should refrain from automatic dismissal of inadequate complaints, and should instead make a factual determination as to whether a sufficient factual basis to warrant the allowance of discovery has been alleged.” *Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp.2d 70, 79–80 (D. Mass. 1998) (citing *New Eng. Data Servs. v. Becher*, 829 F.2d 286, 291–92 (1st Cir. 1997)).

Here, SRT alleges, at least, the following predicate acts committed by Defendants constitute mail and/or wire fraud in furtherance of their fraudulent criminal schemes: (i) submitting two IPR petitions to the PTAB via wire, FAC, ¶¶ 337, 355, 366; (ii) transmitting documents and making payments to the American Arbitration Association for administrative fees via wire, *id.*, ¶¶ 337, 366; (iii) distributing materials with false information about the spinoff of 2seventy via wire and mail, *id.*, ¶¶ 337, 261–99, 366; (iv) transmitting numerous press announcements about the spinoff of 2seventy via wire and mail, *id.*, ¶¶ 337, 261–99, 278–80, 366; and, (v) on numerous occasions, submitting willfully false information to the FDA in violation of 18 U.S.C. § 1001,

id., ¶¶ 300–18, 337, 366. The FAC’s detailed allegations are sufficient here. *See, e.g., In re Lupron*, 295 F. Supp.2d at 165 (“The term false or fraudulent means...untrue when made with reckless indifference to their truth...direct false statements as well as half-truths and the knowing concealment of facts”). The FAC also provides details about Defendants’ intent to defraud. *See, e.g.*, FAC, ¶¶ 247–60 (detailing how Defendants made intentional misrepresentations and/or omissions of material facts in order to induce SRT into entering into the Release provisions of the Settlement Agreement, and but-for Defendants’ actions, SRT would not have entered into the Settlement Agreement); ¶ 18 (alleging intent to deprive SRT of its business, property and money); ¶¶ 276–77, 280 (alleging fraudulent scheme with the intent to harm SRT and eliminate bluebird’s competition); ¶ 311 (alleging Defendants’ intent to submit false information about SRT’s drug product to the FDA). Courts within this Circuit have held that allegations of mail and/or wire fraud have been permitted to proceed in the face of far less. *See, e.g., In re Lupron*, 295 F. Supp.2d at 165; *Ferrer v. Int’l Longshoremen’s Ass’n*, No. 08-cv-1505, 2009 WL 1361953, at **5–6 (D.P.R. May 11, 2009) (plaintiffs adequately alleged mail and wire fraud by claiming that defendants sent various letters through mail and facsimile containing false statements that were designed to discourage plaintiff from performing certain duties as a union member); *AngioDynamics*, 2019 WL 10787926, at *15 (D. Mass. Sept. 25, 2019) (denying motion to dismiss RICO mail and wire fraud claims, although “Plaintiff has not identified specific shipments by time, but Plaintiff has identified them by place and content”); *New England Data Servs., Inc. v. Becher*, 829 F.2d 286, 291 (1st Cir. 1987) (denying motion to dismiss, explaining: “Where there are multiple defendants . . . the burden on the plaintiff to know exactly when the defendants called each other or corresponded with each other, and the contents thereof, is not realistic. Plaintiff here provided an outline of the general scheme to defraud and established an inference that the mail or

wires was used to transact this scheme; requiring plaintiff to plead the time, place and contents of communication . . . seems unreasonable.”). Accordingly, Defendants’ arguments that SRT’s mail and wire fraud claims are deficient are without merit.

SRT has sufficiently alleged that Defendants committed mail and wire fraud related to the Settlement Agreement and other activities. With respect to the predicate acts related to the Settlement Agreement, Defendants wrongly claim that (i) the Parties “disagreement” about whether the Settlement Agreement barred SRT’s infringement claims cannot constitute a scheme to defraud as required to establish a RICO predicate act of mail or wire fraud, (ii) “none of SRT’s fraud allegations specify the time, place, or content of the alleged misrepresentations” as required under Rule 9(b); and (iii) SRT has failed to adequately allege “a legal, professional[,] or contractual duty of disclosure.” ECF 57 at 21–22. Defendants also wrongly claim that “[l]egal positions are not material falsehoods that would support wire [or mail] fraud.” *Id.* at 21. While a “disagreement” regarding the provisions of the Settlement Agreement cannot in-itself constitute a “scheme to defraud” under the mail and wire fraud statutes, the FAC makes clear that a “disagreement” is not what SRT is alleging. The FAC alleges that, but-for Defendants’ willful misrepresentations regarding the Settlement Agreement and their continued concealment of their fraudulent acts, SRT would have never released its claims against Defendants Leschly, bluebird, and Third Rock.

Defendants’ claims that none of SRT’s fraud allegations with respect to the Settlement Agreement specify the time, place, or content of the alleged misrepresentations are without merit. To the contrary, in addition to alleging time and place, SRT has specifically set forth the content of each of Defendants’ alleged misrepresentations (*i.e.*, what each of the Defendants did to deceive SRT into entering into the Settlement Agreement), how they deceived SRT, and how Defendants involved the mails and/or wires in carrying out their misrepresentations. *See* FAC, ¶¶ 247–60, 337,

366. Such allegations are more than sufficient to state claims for mail and/or wire fraud. *See, e.g.*, *Sebago*, 18 F. Supp.2d at 80; *Williams v. Affinion Grp., LLC*, 889 F.3d 116, 125 (2d Cir. 2018) (“a detailed description of the underlying scheme and the connection therewith of the mail and/or wire communications is sufficient to satisfy Rule 9(b)”) (internal citations and quotation marks omitted); *AngioDynamics*, 2019 WL 10787926, at *15 (denying motion to dismiss RICO mail and wire fraud claims.); *New England Data*, 829 F.2d at 291 (denying motion to dismiss RICO mail and wire fraud claims.).

Defendants’ argument that SRT fails to adequately allege “a legal, professional[,] or contractual duty of disclosure” ignores the well-settled law of this Circuit. “Whether one views the defendants’ actions as involving the dissemination of information that was wholly false, or false because of an incomplete depiction of the truth, they are actionable under the mail and wire fraud statutes.” *Lupron*, 295 F. Supp.2d at 167–68 (“[T]his is a case of affirmative misrepresentation. And because the alleged misrepresentations were knowing, deliberate, and made in furtherance of a scheme to defraud, they are sufficient to support the predicate acts of mail and wire fraud.”). And, Defendants’ reliance on *Lu* is misplaced. ECF 57 at 21 (quoting *Lu v. Menino*, 98 F. Supp.3d 85, 98–99 (D. Mass. 2015)). Unlike the plaintiff in *Lu*, SRT is not alleging that Defendants’ legal positions are the actions that constitute mail and/or wire fraud. Rather, SRT clearly satisfied the mail and wire fraud statutes by alleging that Defendants knowingly made omissions of material fact without which SRT would not have entered into the Settlement Agreement. FAC, ¶¶ 247–60; *see Sebago*, 18 F. Supp.2d at 80; *Lupron*, 295 F. Supp.2d at 167–68.

SRT sufficiently alleges that Defendants committed mail and wire fraud in connection with their serial false statements to the FDA concerning the orphan drug designation of SRT’s drug

product. FAC, ¶¶ 300–18, 337, 366. SRT specifically alleges that Defendant Thompson, along with the Leschly Enterprise, “conspired to sabotage the TNS9 IND and interfere with SRT’s ability to complete its FDA regulatory submissions through Thompson directing and causing MSK to intentionally withhold TNS9 IND documents from SRT and willfully falsify information on the TNS9 IND Forms submitted to the FDA.” FAC, ¶¶ 307 (emphasis added), ¶¶ 308–18. Defendants’ contention that “[a]ctivity cannot amount to a private claim of mail and wire fraud where the effective reach of the deception stopped at a third-party regularly body[,]” *see* ECF 57 at 23, is contrary to well-settled law. *See Lupron*, 295 F. Supp.2d at 168 (quoting *U.S. v. Christopher*, 142 F.3d 46, 54 (1st Cir. 1998) (“[n]othing in the mail and wire fraud statutes requires that the party deprived of money or property be the same party who is actually deceived.”)). While Defendants argue that orphan drug designation is a separate process from seeking approval of a drug through an investigation new drug application, ECF 57 at 23, SRT alleges that Thompson and the Leschly Enterprise directed MSK to submit the false information about SRT’s drug product to the FDA. FAC, ¶¶ 300–18, Ex. 42-9–42-13 (copies of the false forms). These allegations are adequate to survive a motion to dismiss, especially since additional facts concerning the false FDA submissions are more appropriately determined at the discovery stage. *See Sepulveda-Villarini v. Dep’t of Educ. of P.R.*, 628 F.2d 25, 30 (1st Cir. 2010) (“[a] plausible but inconclusive inference from pleaded facts will survive a motion to dismiss”).

SRT has sufficient alleged that Defendants committed mail and wire fraud related to the spinoff of 2seventy. Without merit, Defendants argue that (i) any fraudulent aspect of their 2seventy spinoff is entirely contingent on SRT separately establishing an underlying fraud which it cannot do; (ii) SRT fails to allege how 2seventy’s financial statements related to its spinoff from bluebird were intended to deceive anyone; and (iii) “SRT cannot rely on any conduct that would

have been actionable as securities fraud as a predicate RICO act.” ECF 57 at 24–25. To the contrary, SRT’s allegations unquestionably establish an underlying fraud. *See* FAC, ¶¶ 261–99. SRT also alleges, in detail, how 2seventy’s announcements were deceptive to the public at large, and contributed to the RICO enterprise, by claiming that Defendants publicly falsely described 2seventy as a “spinoff” of “bluebird’s oncology programs,” when it was, in reality, simply a way to hide bluebird’s assets and protect Defendants’ unlawful financial gains. *See* FAC, ¶¶ 263–89. *See Christopher*, 142 F.3d at 54. To be clear, SRT is not claiming that Defendants engaged in securities fraud as a predicate act related to 2seventy, but rather that they committed mail and wire fraud related to 2seventy’s spinoff.

SRT has sufficiently alleged a pattern of racketeering activity. A pattern of racketeering activity “requires at least two acts of racketeering activity, . . . the last of which occurred within ten years . . . after the commission of a prior act of racketeering activity.” 18 U.S.C. § 1961(5). In addition, a plaintiff must allege “(1) whether the acts are related; and (2) whether they could be found to amount to or pose a threat of continued criminal activity.” *Fleet*, 893 F.2d at 444. A plaintiff establishes, like SRT has done here, “that predicate acts are related by demonstrating that they ‘have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events.’” *Id.*, at 445 (quoting *H.J. Inc. v. Northwestern Bell Telephone Co.*, 492 U.S. 229, 240 (1989)). SRT has “establish[ed] continuity by demonstrating that the predicate acts amount to continued criminal activity[,]” or, alternatively, that the predicate acts, though not continuous, threaten to become so. *Id.* at 446 (emphasis added). “[A] plaintiff can show continuity in one of two ways. Under the ‘closed’ approach, a plaintiff would have to prove a ‘closed period of repeated conduct’ that ‘amounted to . . . continued criminal activity.’” *Home Orthopedics Corp. v. Rodriguez*, 781 F.3d

521, 528 (1st Cir. 2015) (quoting *H.J. Inc.*, 492 U.S. at 241). Applying the principles of closed-ended continuity, the First Circuit has “taken a jaundiced view of alleged patterns lasting less than two years[,]” holding that, in order to constitute patterns of RICO activity, such cases must also allege more than a few acts or a single victim and/or have the potential to continue into the future. *Divot Golf Corp. v. Citizens Bank of Mass.*, No. 02-CV-10654, 2002 WL 31741472, at *5 (D. Mass. Nov. 26, 2002) (collecting cases). “Alternatively, under the open-ended approach, a plaintiff can satisfy the continuity requirement by showing past conduct that by its nature projects into the future with a threat of repetition.” *Rodriguez*, 781 F.3d at 528 (internal quotation marks omitted).

As discussed, SRT alleges multiple predicate acts including, *inter alia*, transmitting a settlement payment and submitting the executed fraudulent induced Settlement Agreement; transmitting numerous press false releases about the 2seventy spinoff; and submitting willfully false information to the FDA. *See, e.g.*, FAC, ¶¶ 373–80, 389–96, 405–12, 423–30. All were carried out by the same participants against the same victim, SRT, with the same or similar goals in mind. *See id.*, ¶ 17. Therefore, each predicate act is sufficiently related in order to constitute a pattern of racketeering. *See, e.g.*, *H.J.*, 492 U.S. at 250 (plaintiffs satisfied the relatedness requirement because the acts of bribery alleged are said to be related to a common purpose); *Fleet*, 893 F.2d at 445. *Contra. Lerner v. Colman*, 26 F.4th 71, 84–85 (1st Cir. 2022) (holding that two alleged predicate acts were not sufficiently related, where the two shared, at best, only a partial overlap in participants, with no common participants having a major role in both schemes; and the victims of each act were different).

While it is only required to allege one of the two, SRT has also adequately alleged both open-ended and closed-ended continuity. The first of Defendants’ predicate acts occurred in November 2020, well within 10 years of the others. *See* FAC, ¶¶ 15–17. Because Defendants will

continue engaging in their fraudulent and unlawful acts, such as false marketing of bluebird’s drug product, or create a new spinoff of 2seventy in order to hide its assets within any subsequent lawsuits, Defendants’ actions are capable of continuing indefinitely. *See H.J.*, 492 U.S. at 242–43; *see also Fleet*, 893 F.2d at 447. Furthermore, SRT alleges that Defendants’ actions are part of their regular way of operating by claiming, *inter alia*, that Defendants have continually submitted falsified information about the vector to the FDA and continually evaded the Settlement Agreement for a significant period of time. *See, e.g.*, FAC, ¶¶ 17, 22, 223, 261, 276, 309–15, 325, 333–37, 339; *see, e.g.*, *H.J.*, 492 U.S. 229, 242–43; *Fleet*, 893 F.2d at 444; *see also Ferrer*, No. 08-cv-1505, 2009 WL 1361953, at *10 (“Although the relevant precedent suggests that a period of eleven months may be too short to establish a pattern of closed-ended continuity, the Court declines to dismiss Plaintiff’s RICO claims on this element alone...”).

SRT has sufficiently alleged causation, with cognizable RICO injuries. In civil RICO cases, a plaintiff must allege that the racketeering activity is the “but-for” and the proximate cause of their alleged damages. *Sebago*, 18 F. Supp.2d at 79. Generally, the issue of proximate cause is one for a jury to decide. *See id.* at 85. Proximate cause as a jury issue notwithstanding, SRT clearly makes such allegations here. *See, e.g.*, FAC, ¶¶ 381, 552–53, 565–66. Contrary to Defendants’ arguments, ECF 57 at 28–29, it is well-settled in this Circuit that litigation costs are cognizable RICO injuries. *See, e.g.*, *Lawson*, 554 F. Supp.3d at 196; *Eagle Inv. Sys. Corp. v. Tamm*, 146 F. Supp.2d 105, 110 n.29 (D. Mass. 2001) (plaintiff adequately alleged injury under RICO where, like SRT here, it alleged that litigation costs were one of the intended consequences of defendants’ predicate acts).

C. SRT Adequately Alleges That Defendants Violated 18 U.S.C. § 1962(c)

Defendants fail to make any specific arguments as to why Count I, alleging a violation of 18 U.S.C. § 1962(c), cannot proceed. Nor can they. Defendants do not contest the fact that they

are individual persons within an enterprise and, for the reasons already set forth, SRT adequately alleges that Defendants conducted a pattern of racketeering activity and that Defendants' RICO violations caused it cognizable injuries. *See* FAC, ¶¶ 367–84; *Doyle & H.P Leasing, Inc. v. Hasbro, Inc.*, 103 F.3d 186, 190 (1st Cir. 1996) (describing requirements for stating a cause of action under § 1962(c)); *Sebago*, 18 F. Supp.2d at 79–85.

D. SRT Adequately Alleges That Defendants Violated 18 U.S.C. § 1962(a)

Regarding RICO-related investments, the statute provides that “[it] shall be unlawful for any person who has received any income derived, directly or indirectly, from a pattern of RICO activity . . . to use or invest, directly or indirectly, any part of such income, or the proceeds of such income [in] the establishment or operation of, any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce.” 18 U.S.C. § 1962(a). “In the First Circuit, the ‘investment use rule’ requires plaintiffs asserting a § 1962(a) cause of action to allege a specific injury flowing from the investment and use of the racketeering proceeds.” *Cavallaro v. UMass Mem'l Health Care, Inc.*, No. 09-40152-FDS, 2010 WL 3609535, at *5 (D. Mass. Jul. 2, 2010). In addition to alleging “a pattern of RICO activity[,]” SRT has sufficiently alleged that Defendants used the income derived therefrom to establish 2seventy, an “enterprise” also engaged in interstate commerce, causing it injuries distinct from the injuries associated with Defendants’ other racketeering acts. *See* FAC, ¶¶ 385–401.

E. SRT Adequately Alleges That Defendants Violated 18 U.S.C. § 1962(b)

Regarding RICO enterprises, the Federal RICO statute provides that “[i]t shall be unlawful for any person through a pattern of racketeering activity . . . to acquire or maintain, directly or indirectly, an interest in or control of any enterprise which is engaged in, or the activities which affect, interstate or foreign commerce.” 18 U.S.C. § 1962(b). As with its 18 U.S.C. § 1962(a) claim, by using the funds derived from their previous racketeering activities to acquire 2seventy

and maintain control of the Leschly Enterprise, SRT has more than sufficiently pled that Defendants “through a pattern of racketeering activity . . . acquire[d] an interest in or control of” an enterprise and that such investment has caused them harm. *See* FAC, ¶¶ 403–17; *Compagnie de Reassurance D’Ille de France v. New Eng. Reins. Corp.*, 57 F.3d 56, 91 (1st Cir. 1995) (noting that, similar to § 1962(a), plaintiffs needed to show that they were harmed by reason of defendant’s acquisition or maintenance of control of an enterprise through a pattern of racketeering activity). Accordingly, Count III should also be permitted to proceed.

F. SRT Adequately Alleges That Defendants Violated 18 U.S.C. § 1962(d)

“To state a RICO conspiracy claim pursuant to § 1962(d), the plaintiff must allege (1) the existence of an enterprise affecting interstate commerce, (2) that the defendant knowingly joined the conspiracy to participate in the conduct of the affairs of the enterprise, (3) that the defendant participated in the conduct of the affairs of the enterprise, and (4) that the defendant did so through a pattern of racketeering activity by agreeing to commit, or in fact committing, two or more predicate offenses.” *Sebago*, 18 F. Supp.2d at 85; *see also Velazquez-Fontanez*, 6 F.4th at 212. As discussed, SRT has adequately alleged an enterprise affecting interstate commerce (*i.e.*, the “Leschly Enterprise”) and that each of the Defendants knowingly participated in the conduct of the affairs of the Leschly Enterprise; and that each of the Defendants agreed to commit at least two predicate acts. FAC, ¶¶ 18, 339, 343–59, 366. While Defendants argue that that RICO Count IV separately fails because a RICO conspiracy under 18 U.S.C. § 1962(d) cannot be established where the pleadings do not state a substantive RICO claim, ECF 57 at 30, this is clearly not the case here.

II. DEFENDANTS’ MOTION TO DISMISS THE FEDERAL ANTITRUST CLAIMS SHOULD BE DENIED

Defendants have not challenged any element of a Sherman Act violation. *U.S. v. Grinnell*, 384 US 563, 570–71 (1966); *Spectrum Sports, Inc. v. McQuillan*, 506 US 447, 456–57 (1993); *Lee*

v. Life Ins. Co. of N. Am., 829 F. Supp. 529, 535 (1993); *Volvo N. Am. v. Men's Intern. Pro. Tennis Coun.*, 857 F.2d 55, 74 (2d Cir. 1998) (all citing the elements required to state specific types of anti-trust claims, none of which Defendants address). This is not surprising, as the FAC alleged violations of monopolization (Count V), attempted monopolization (Counts VI–VII), and conspiracy (Counts VIII–IX) under 15 U.S.C. § 2, conspiracy (Count X) under 15 U.S.C. § 1, and presented evidence of each. *E.g.*, FAC, ¶¶ 435–544. Therefore, Defendants do not dispute monopoly power, anticompetitive conduct, conspiracy, or harm to SRT. Rather, Defendants claim there is no remedy for these violations under the doctrine of “antitrust injury,” release and time-bar, and the First Amendment. Defendants’ arguments fail, especially given that all facts and all reasonable inferences from those facts are construed in the light most hospitable to SRT. *US ex rel. Hutcheson*, 647 F. 3d at 383–84.

A. “Antitrust Injury” Does Not Bar Suit

“Antitrust injury” concerns standing: who can sue for the violation. *Volvo N. Amer.*, 857 F. 2d at 66–68. However, “[c]ompetitors and consumers in the market where trade is allegedly restrained are presumptively the proper plaintiffs to allege antitrust injury.” *Serpa Corp. v. McWane, Inc.*, 199 F.3d 6, 10–11 (1st Cir. 1999). “In contrast, a commercial intermediary, such as a distributor or sales representative, generally lacks standing because its antitrust injury is too remote.” *Id. Cf. In re Microsoft Corp. Antitrust Lit.*, 127 F. Supp.2d 702, 711 (D. Md. 2001) (“If, as plaintiffs allege, Microsoft unlawfully prevented competitors from effectively developing and marketing a product, those competitors would be more direct victims of Microsoft's antitrust violations.”). Here, there is no dispute SRT is a competitor of Defendants, having a competing product delayed through anticompetitive means while Defendants cornered the market. FAC, ¶¶ 435–544. Apart from the high bar of securing dismissal and the ample evidence in the FAC, the “traditional rule excusing antitrust plaintiffs from an unduly rigorous standard of proving antitrust

injury” counsels against dismissal due to “the inequity of a wrongdoer defeating the recovery of damages against him by insisting upon a rigorous standard of proof.” *J. Truett Payne Co. v. Chrysler Motors Corp.*, 451 US 557, 565–68 (1981). *Cf. Hosp. Bldg. Co. v. Trustees of Rex Hosp.*, 425 U.S. 738, 746–47 (1976) (“[I]n antitrust cases, where the proof is largely in the hands of the alleged conspirators, dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly.” (internal quotation and citations omitted)). Again, Defendants do not dispute the violations occurred but rather “antitrust injury.”

Defendants’ sole argument is “there is no antitrust injury when a plaintiff’s allegation is that it should have the defendant’s place in the relevant market.” ECF 57 at 32. In particular, “there is no injury when an antitrust plaintiff merely wants to substitute itself for the defendant in the marketplace.” *Id.* at 33. Defendants’ argument misrepresents the FAC and is wrong on the law. The FAC does not allege unlawful competition based on a single monopoly, which makes Defendants’ entire argument flawed. Indeed, the passages cited (but not quoted) by Defendants, ECF 57 at 32–33, make clear the FAC alleged unlawful competition on the market rather than competition for a single slot:

“excluding ***alternative*** lentiviral vector gene therapy treatments,” and forcing payers to “pay exorbitant amounts (e.g., \$2.8 million per treatment) to bluebird instead of substantially lower amounts” to SRT, FAC, ¶ 464;

“***delayed*** launch of a ***competing***… lentiviral vector gene therapy[,]” *id.*, ¶ 488;

“***delay*** SRT from ***entering*** the market for lentiviral vector gene therapy… with a substantially ***lower cost product***[,]” *id.*, ¶ 507;

“Defendants goal was ***not simply to gain market share***, but to ***eliminate the competition and obtain total monopoly*** through improper means[,]” *id.*, ¶¶ 514, 520;

“Defendants’ anticompetitive conduct also substantially suppresses or destroys ***competition***. For example, SRT’s TNS9 drug product would have been available… first but for the anticompetitive . . . [,]” *id.*, ¶ 538.

While SRT should have launched first, the FAC expressly alleges that “SRT and Defendants would have shared the relevant market and fairly competed in the market but for” Defendants’

anticompetitive actions. FAC, ¶ 539. The FAC makes clear that Defendants anticompetitive acts delayed SRT's gene therapy treatment with a substantially reduced price (e.g., \$2.1 million dollars less than Defendants' treatment). *Id.*, ¶¶ 441–49. As a result, Beta Thalassemia patients and their insurance providers are forced to pay Defendants' exorbitant price of \$2.8 million instead of being able to be treated with SRT's lower-priced gene therapy lentiviral vector. *Id.* Indeed, at launch, the price of bluebird's treatment increased by more than 300% from estimates prior to launch when SRT was ahead of bluebird in development. *Id.* These allegations must be accepted as true, and in any event, are not challenged by Defendants. Such allegations are also typical antitrust injuries.

See, e.g., Hewlett-Packard Co. v. Boston Sci. Corp., 77 F. Supp.2d 189, 198–99 (D. Mass. 1999) (“Antitrust laws were designed to protect the competitive process that brings to consumers the benefits of lower prices, better products, and more efficient production methods When a defendant engages in anticompetitive acts in an attempt to gain a monopoly, the competitor who is being driven out of the market has standing.”); *U.S. v. Microsoft Corp.*, 253 F. 3d 34, 79 (D.C. Cir. 2001) (“[I]t would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will.”); *Cal. Assoc. of Realtors, Inc. v. PDFfiler, Inc.*, No. 16-11021-IT, 2018 WL 1403330, at **15–16 (D. Mass. 2018) (denying motion to dismiss where defendant blocked competitor's product and denied consumers choice to choose that product); *Morales-Villalobos v. Garcia-Llorens*, 316 F.3d 51, 55 (1st Cir. 2003) (“[I]t is not apparent, on a motion to dismiss, why [plaintiff] lacks antitrust standing. She claims to be directly injured by exclusion”); *Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F.Supp. 2d 750, 772 (D.N.J. 1999) (“[T]he intentional attempt to exclude competitors from the market and maintain monopoly power...is precisely the type of injury that the antitrust laws were intended to prevent.”); *Primetime 24 Joint Venture v. National Broadcasting, Co., Inc.*, 219 F.3d 92, 103–04 (2d Cir.

2000) (antitrust injury due to harm to plaintiff, *e.g.*, lost profits, and harm to competition, *e.g.*, price competition).

Defendants cherry-pick quotes from the FAC referring to “market exclusivity” in an intentionally misleading way. ECF 57 at 32–33; FAC, ¶¶ 320–21. The orphan drug “market exclusivity” here does not prevent SRT’s TNS9 drug product and bluebird’s BB305 drug product from being on the market at the same time because the TNS9 and BB305 are not the same drug product. *See* 21 CFR §316.3(b)(12). Indeed, counsel for Defendants recognized that bluebird’s “market exclusivity” granted by the FDA does not block SRT from being on the market together with bluebird. During the 2023 arbitration proceeding, when the arbitrator asked if bluebird’s exclusivity prevents approval of SRT’s TNS9 gene therapy treatment, counsel for Defendants stated:

That is this fiction that somehow SRT was prevented from getting approval for its TNS9 technology vector because of bluebird’s approval. I can assure you with 100 percent certainty that that is wrong. [T]he type of generic... called a biosimilar... That is the only thing that is blocked by an orphan drug exclusivity. This is about the most basic thing that you know about exclusivity related to drug products. It does not block SRT.... ***It does not block SRT*** from getting its own approval if it does its own clinical studies.... ***Are you trying to rely on my data in order to get approval from the FDA, that’s what copy is in this context.*** That’s the only thing that orphan drug exclusivity matters to.

Ex. 2, 303:4–306:5. As alleged in the FAC, Defendants conspired with Thompson (former CEO of MSK), who directed and caused MSK to obstruct SRT’s regulatory efforts and insert knowingly false information that is material to SRT’s TNS9 drug product to the FDA in furtherance of Defendants’ scheme to sabotage and delay SRT’s entry into the gene therapy market for Beta Thalassemia. FAC, ¶ 457, Ex. 42-9 –42-13 (copies of false FDA submissions).

Because the FAC does not allege competition to obtain a monopoly, Defendants’ cases are inapplicable. Defendants’ reliance of *Riegel*, ECF 57 at 32–34, is outdated as this case was clarified by the Seventh Circuit two years later in *Fishman v. Estate of Wirtz*, 807 F. 2d 520, 533

(7th Cir. 1986). In *Fishman*, the claimant tried to argue “the substitution of one competitor for another does not injure competition” only to be told “[t]he case law, however, does not support such a broad contention” and “competition to acquire a natural monopoly” still violates the Sherman Act. *Fishman*, 807 F. 2d at 533. Notably, Hon. Maureen K. Ohlhausen, Chair of the Federal Trade Commission observed, that “substitution” bar is the “minority view” and the “more common view” is harm to competition results even if there can be only one monopoly in the end. 20 STAN. TECH. L. REV. 93 (2017). In other words, “a race to a throne” (i.e., single slot exclusivity), while not applicable here, is still a competition.

B. “Release” Does Not Bar Suit

There was no “release” of the antitrust claims. The 2020 Settlement Agreement was limited to claims “from the beginning of the world to the Parties’ execution of [the] Settlement Agreement.” FAC, ¶ 210. The Settlement Agreement did not release causes of action occurring *after* execution on November 2, 2020. *Id.*, ¶ 210.³ Indeed, Defendants’ reliance on “may have” as “future-oriented” is a misleading crop quote from just before the temporal limitation “from the beginning of the world to the Parties’ execution of this [agreement].” ECF 57 at 34; FAC, ¶ 210. In fact, Defendants bluebird and Third Rock lost on this very point in the January 2023 arbitration against SRT. FAC, ¶¶ 237–40. The Settlement Agreement does not insulate future conduct any more than settling with an attempted murderer permits future attempted murders. Regardless, Defendants cannot rely on the Settlement Agreement’s release to insulate conduct arising after its execution. *See Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc.*, 473 U.S. 614, n.19

³ The Settlement Agreement is governed by the laws of the State of New York. ECF 36-1, ¶ 6. Under well-settled New York law, “a general release”—like the one here—only “bars recovery on any cause of action arising prior to its execution.” *Peterson v. Regina*, 935 F. Supp.2d 628, 636 (S.D.N.Y. 2013) (quoting *Lambert v. Skylar*, 877 N.Y.S.2d 452, 453 (N.Y. App. Div. 2009)); *Murray-Gardner Mgmt. v. Iroquois Gas Transmission Sys., L.P.*, 646 N.Y.S.2d 418, 419–20 (N.Y. App. Div. 1996).

(1985) (If an agreement operated as “a prospective waiver of a party's right to pursue statutory remedies for antitrust violations, we would have little hesitation in condemning the agreement as against public policy.”).

It is undisputed that monopolization (Count V) and attempted monopolization (Count VI) accrued in 2022—after execution of the 2020 Settlement Agreement. For example, monopolization requires “monopoly power” and attempted monopolization requires “dangerous probability of achieving monopoly power.” *Grinnell*, 384 US at 570–71; *McQuillan*, 506 US at 456–57. As alleged in the FAC, “Defendants obtained their monopoly power in 2022 with the commercial launch of bluebird’s Zytteglo (BB305) in the United States” and “there is a dangerous probability of success in achieving monopoly power with the launch of Zytteglo (BB305) in 2022.” FAC, ¶¶ 439, 484. Defendants do not dispute these facts, nor could they with all facts and inferences taken in SRT’s favor. As such, there is no dispute the causes of action for monopolization (Count V) and attempted monopolization (Count VI–VII) occurred in 2022—after the date cutoff of the 2020 Settlement Agreement.

It is also undisputed that the conspiracy under 15 U.S.C. §2 (Counts VIII–IX) and 15 U.S.C. §1 (Count X) involved conduct after execution of the 2020 Settlement Agreement. As an initial matter, Defendants’ “antitrust injury” argument is inconsistent with the release. As discussed above, the FAC alleges harm to SRT and harm to competition with the launch of Zytteglo in 2022 while engaging in anticompetitive conduct to keep SRT off the market for as long as possible. If the antitrust claims could not have been brought earlier than 2022, they could not have been released in 2020. Regardless, the FAC alleges Defendants’ overt acts of post-release conspiracy such as launching Zytteglo in 2022, seeking expedited launch against Sickle Cell Disease in 2023, and continuing to delay competition from SRT. See, e.g., FAC, ¶¶ 439, 449, 499,

513–14, 519–20, 532–34, 536. This post-release conduct, at minimum, gives rise to post-release causes of action which were not (and could not) be released. *Zenith Radio Corp. v. Hazeltine Rsch. Inc.*, 401 US 321, 338 (1971) (“each time a plaintiff is injured by an act of the defendants a cause of action accrues to him to recover the damages caused by that act”); *Mitsubishi Motors Corp.*, 473 U.S. 614, n.19 (1985)

Defendants “time-bar” arguments likewise fail. The statute of limitations on SRT’s antitrust actions is “four years after the cause of action accrued.” 15 U.S.C. § 15b. As discussed, SRT’s causes of action accrued within the last four years. The FAC alleges anticompetitive conduct that occurred less than four years ago, rendering moot Defendants’ meritless claim that the conduct began earlier. *See Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 502 n. 15 (1968) (“[W]e are dealing with conduct which constituted a continuing violation of the Sherman Act and which inflicted continuing and accumulating harm on [the plaintiff]. Although [the plaintiff] could have sued in 1912 for the injury then being inflicted, it was equally entitled to sue in 1955.”); *see also Zenith Radio Corp.*, 401 US at 338–42 (permitting antitrust plaintiff to “recover in its 1963 suit for damages suffered after June 1, 1959, as the consequence of pre-1954 conspiratorial conduct”, noting measurement is from when the cause of action accrues). SRT could not have brought these antitrust claims in 2011–2012 (the period identified by Defendants) or even 2019 (just prior to the statute of limitations) because Defendants’ unlawful anticompetitive occurred after November 2020. And, SRT’s antirust injury occurred with the launch Zynteglo in 2022 in connection with Defendants’ efforts to delay SRT’s competing drug product in market. The elements of the monopolization and attempted monopolization as violations were not even met until the launch of Zynteglo in 2022. Indeed, SRT could not have even alleged antitrust conspiracy to launch Zynteglo while keeping SRT off the market, given Defendants announced

the FDA submission for Zytteglo in 2021 and received approval and launched with supracompetitive prices in 2022. FAC, ¶ 223.

C. “First Amendment” Does Not Bar Suit

Defendants’ First Amendment defense confuses the issues. For example, Defendants justify their “conspiracy to shut down SRT as a competitor . . . and obtain FDA approval for” its own product because “[o]btaining FDA approval is the quintessential petitioning conduct.” ECF 57 at 36. The issue is not the bare petitioning for FDA approval, but rather the unlawful conduct surrounding it. Even assuming the antitrust violations were somehow subject to the First Amendment, “[i]t is well settled that First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute.” *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 US 508, 514 (1972). “An antitrust violation does not enjoy immunity simply because an element of that violation involves an action which itself is not illegal.” *Clipper Express v. Rocky Mountain Motor Tariff Bureau*, 690 F. 2d 1240, 1263 (9th Cir. 1982).

Likewise, Defendants argue the First Amendment protects “fraudulent inducement of SRT in connection with the Settlement Agreement.” ECF 57 at 36. Again, that is not the law. *Cal. Motor Transp.*, 404 US at 514; *Clipper Express*, 690 F. 2d at 1263. None of Defendants cases support it. *Allied Tube* was discussing “anticompetitive activity intended to influence the government” relating to a publicity campaign, and distinguished “commercial activity that has traditionally had its validity determined by the antitrust laws themselves.” *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 US 492 (1988). Moreover, the court went on to note absurd results if taken too far, such as justifying anticompetitive conduct and conspiracies. *Id.*, 506–07. *Freeman* concerned antitrust liability for refusal to settle a case and noted it was derivative of whether the case was a sham. *Freeman v. Lasky, Haas & Cohler*, 410 F. 3d 1180, 1185 (9th Cir. 2005). It did not say, as Defendants claim, settlement talks are “entitled to immunity absent a showing that the talks were

a sham.” ECF 57 at 36. And, even if Defendants are correct, fraudulently inducement *is* a sham. *Storage Tech.* and *Ecodisc* concerned a letters threatening litigation. *Storage Tech. Corp. v. Custom Hardware Eng’g & Consulting, Ltd.*, No. CIV.A. 02-12102-RWZ, 2006 WL 1766434, at *35 (D. Mass. June 28, 2006); *EcoDisc Tech. AG v. DVD Format/Logo Licensing Corp.*, 711 F. Supp. 2d 1074, 1082 (C.D. Cal. 2010). In short, there is no authority permitting one party to use fraud to induce another into signing a settlement agreement. It is deeply troubling Defendants claim that.

Defendants also claim the submission of “materially false information about the TNS9 drug product to the FDA” is protected. ECF 57 at 37. Again, that is not the law. *Cal. Motor Transp.*, 404 US at 514; *Clipper Express*, 690 F. 2d at 1263. Defendants cite *United Food*, but that involved asking whether a patent was procured by fraud. *United Food & Com. Workers Unions & Emps. Midwest Health Benefits Fund v. Novartis Pharm. Corp.*, 902 F.3d 1, 9 (1st Cir. 2018). Moreover, the *United Food* case held “an unmistakably false affidavit” would be *per se* material, and there is no dispute the FDA forms—signed under penalty of perjury—are unmistakably false. *See id. Cf. Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F. 3d 1276, 1292 (Fed. Cir. 2013) (“[A] patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent.”); FAC, Ex. 42-9–42-13. Even if applicable, Defendants argument as to materiality is a fact dispute: “checkmark box indicating that a product does not have FDA orphan drug designation materially affect the timing of FDA approval.” ECF 57 at 37. Defendants offer no support for this, and in any event, all facts and inferences are to be taken in Defendants’ favor. Indeed, Defendants argue “approval and orphan drug designation are separate FDA processes,” but the forms at issue were submitted in connection with SRT’s investigation new drug application. *See* FAC, Ex. 42-9–42-13. It is a reasonable

inference that falsely answering “[i]s this indication for a rare disease (prevalence <200,000 in U.S.)?” and “[d]oes this product have an FDA Orphan Designation for this indication?” with “[n]o” delayed SRT. *See id.* (Field 7A) Indeed, the forms falsely claimed this was a “research” rather than “commercial” IND. *See id.* (Field 6B). Moreover, these forms were submitted without SRT’s authorization and withheld from SRT. FAC, ¶¶ 311–15. There is a clear fact dispute as to whether this conduct delayed or attempted to delay SRT and protect Defendants.

Defendants arguments are especially troubling: unlawful conduct is permitted as long as there is also a petition and the petition is not a sham; fraudulent inducement into a contract is permitted as long as there is also a litigation and the litigation is not a sham; perjury to the federal government is permitted. That is not the law or conduct this Court should endorse under the First Amendment. *Calif. Motor Transp.*, 404 US at 514; *Clipper Express*, 690 F. 2d at 1263.

III. DEFENDANTS’ MOTION TO DISMISS THE FRAUDULENT INDUCEMENT CLAIM SHOULD BE DENIED

SRT also adequately alleges a claim for fraudulent inducement by alleging that Defendants made false representations and omissions of material fact in order to induce it to agree to the Mutual Release and Dispute Resolution Provisions within the Settlement Agreement. *See* FAC, ¶¶ 545–54. In order to state a claim for fraudulent inducement, a plaintiff must allege the following: “(1) defendant made a misrepresentation as to a material fact; (2) such misrepresentation was false; (3) defendant intended to deceive plaintiff; (4) plaintiff believed and justifiably relied upon the statement and was induced by it to engage in a certain course of conduct; and (5) as a result of such reliance plaintiff sustained pecuniary loss.” *Digilytic Int’l Fze v. Alchemy Finance, Inc.*, No. 20 Civ. 4650(ER), 2022 WL 912965, at *7 (S.D.N.Y. Mar. 29, 2022) (quoting *Stephenson v. PricewaterhouseCoopers, LLP*, 482 F. App’x 618, 622 (2d Cir. 2012)). The complaint should “state with particularity the circumstances of the fraud under Rule 9(b) and contain sufficient facts,

accepted as true, to state claims for relief for common-law fraud that are facially plausible under Rule 8(a)(2)." *Id.* (quoting *Woori Bank v. RBS Sec., Inc.*, 910 F. Supp.2d 697, 700–01 (S.D.N.Y. 2012)). "A successful fraudulent inducement claim [involving a contract] should be 'premised on misrepresentations [of material fact] that were made before the formation of the contract and that induced the plaintiff to enter the contract.'" *Id.* (quoting *Cohen v. Koenig*, 25 F.3d 1168, 1173 (2d Cir. 1994)). This is exactly what SRT alleges occurred here.

Specifically, SRT alleges that, "in 2020, prior to the execution of the Settlement Agreement, Defendants made false statements and omissions of material fact" while knowing that their "representations were false and that SRT would reasonably rely on" them and "with the intent of inducing SRT to entering into the Dispute Resolution provision" and executing the Settlement Agreement. *See* FAC, ¶¶ 547–51. Such misrepresentations of material fact and/or omissions include, *inter alia*, Defendants Thompson, Leschly, and bluebird's false representations that SRT would be the only company to operate within the scope of the claims of the intellectual property in the 2005 Agreement (even though they presently knew that "their upcoming BB305 product did and would operate within the scope of the claims of the intellectual property in the 2005 Agreement"); Defendants Thompson, Leschly, and bluebird's false representations that the SRT's licensed patents were valid and enforceable against bluebird and that they had waived all rights to challenge the validity of patents; and failure to disclose the material fact that Thompson agreed to have MSK to cooperate with bluebird in challenging the validity and enforceability of the SRT's licensed patents. FAC, ¶¶ 248–53. SRT relied upon Defendants' misrepresentations and/or omissions by executing the Settlement Agreement, with the Release and Dispute Resolution provisions; and such reliance was reasonable because, at the time of the Settlement Agreement, bluebird had a claim against MSK challenging the validity of SRT's licensed patents. *Id.*, ¶¶ 254–

55. As a result of Defendants' material omissions and false representations, SRT gave up viable causes of action in the Massachusetts Litigation, and "incurred substantial legal fees in connection with asserting its legal rights under the Settlement Agreement[.]" *Id.*, ¶¶ 258–59, 552–54. Such allegations are more than sufficient to state a claim for fraudulent inducement. *See Digilytic*, 2022 WL 912965, at *8; *see also Merrill Lynch & Co., Inc. v. Allegheny Energy, Inc.*, 500 F.3d 171, 181 (2d Cir. 2007) (where, as here, "the misrepresentations made [by the defendant] relate to matters peculiarly within the [defendant's] knowledge [then] the wrong party may rely on them without further investigation"); *Turner v. Johnson & Johnson*, 809 F.2d 90, 102 (1st Cir. 1986) (lost value of a business may be a "measure of damages for fraudulent inducement into [a] contract").⁴

Each of Defendants' arguments as to why SRT's fraudulent inducement claim should be dismissed, *see* ECF 57 at 37–38, is meritless. By specifically explaining why Defendants' alleged misrepresentations were false or fraudulent (e.g., Defendants' false representation to not challenge the validity and enforceability of the licensed patents), SRT has clearly satisfied Rule 9(b)'s more stringent pleading standards. *See Capax Discovery, Inc. v. AEP RSD Investors, LLC*, 285 F. Supp.2d 579, 588–89 (W.D.N.Y. 2018) (denying motion to dismiss where, as SRT does here, plaintiffs collectively specified the statements they believed to be fraudulent); *Digilytic*, 2022 WL 912965, at *8.

⁴ Similarly, in order to state a claim for fraudulent inducement by way of omission under New York law, "a party must allege all of the following four elements: (1) the opposing party's concealment of information that she had a duty to disclose; (2) the opposing party's intention to defraud, or *scienter*; (3) the pleading party's reliance on his resulting mistaken impression; and (4) damages." *Nash v. The New Sch.*, No. 05-Civ-7174, 2009 WL 1159166, at *3 (S.D.N.Y. Apr. 29, 2009). The FAC sufficiently meets these elements. Furthermore, a party has a duty to disclose where, as Defendants did here, a defendant makes a partial and/or ambiguous statement that would be misleading absent further disclosure. *See Bollinger Indus. Inc. v. Walter R. Tucker Enters., Ltd.*, No. 3:20-CV-95, 2021 WL 5585795, at *6 (N.D.N.Y. Sept. 29, 2021).

Defendants go onto argue that “SRT merely alleges Defendants defrauded it through misrepresentations and omissions regarding what they supposedly agreed they would do in the future” and that a viable claim of fraud concerning a contract must allege misrepresentations of current facts, rather than future intent. ECF 57 at 39–40. Defendants’ arguments misstate the facts alleged, as SRT clearly claims that Defendants misrepresented current facts, as well as their future intent. *See, e.g.*, FAC, ¶¶ 247–53. Defendants’ arguments also misstate well-settled case law. *See, e.g.*, *Digilytic*, 2022 WL 912965, at *7; *see also Wolfson v. Wolfson*, No. 03-0954(RCC), 2004 WL 224508, at *8 (S.D.N.Y. Feb. 5, 2005) (case cited by Defendants holding that “fraudulent inducement requires a misrepresentation of a present fact, and not of a future intent, absent a showing [alleged here] that the defendant has a preconceived and undisclosed intention of not performing as represented”) (internal citations and quotations omitted).

Defendants’ argument that “SRT fails to allege a duty of disclosure” because it does not allege a fiduciary relationship, ECF 57 at 40–41, is similarly baseless. Courts interpreting New York law have found that, even absent any fiduciary relationship, a defendant still owes a plaintiff a duty to disclose where, as here, it makes a partial or ambiguous statement that would naturally require additional disclosure to avoid misleading the plaintiff. *See, e.g.*, *Bollinger*, 2021 WL 5585795, at *6; *see also Donovan v. Aeolian Co.*, 270 N.Y. 267, 272 (1936) (case cited by Defendant explaining that, while “[t]here is no duty upon [a defendant] to speak where silence does not constitute deception[, s]ilence may . . . constitute fraud and deception where the [defendant] has notice that the [plaintiff] is acting upon a mistaken belief as to a material fact”).

Defendants’ argument that SRT’s fraud allegations “are barred by disclaimers[,]” within the 2020 Settlement Agreement expressly disclaiming “reliance on representations not specifically included in the contract[,]” ECF 57 at 41–42, also fails for similar reasons. While the Settlement

Agreement at issue contains a Mutual Release Provision, the release provision only bars claims that SRT had, or could have had, up to and including the execution of the Settlement Agreement. *See ECF 36-1, ¶ 5.* Furthermore, the Release provision did not contemplate SRT’s particularized claim of fraud, involving Defendants’ intentions that could not have been within SRT’s knowledge. *See SRS Cap. Funds, Inc. v. Bujan*, No. 654999/2019, 2020 N.Y. Slip. Op. 31449(U), at *2 (N.Y. Sup. May 4, 2020) (refusing to dismiss plaintiff’s fraudulent inducement claim where, as here, the general disclaimers at issue were “not sufficiently specific to the particular type of fact misrepresented or disclosed, and they concern[ed] facts peculiarly within the [d]efendants’ knowledge”) (internal citations, quotation marks, and alterations omitted). Defendants’ final argument, that SRT waived its fraudulent inducement claim by ratification, ECF 57 at 42, is even more meritless, as the very caselaw they cite specifically indicates the opposite. *See, e.g., Petrello v. White*, 412 F. Supp. 2d 215, 227 (E.D.N.Y. 2006) (“ratification does not preempt a claim for damages arising from the fraud”).

IV. DEFENDANTS’ MOTION TO DISMISS THE MASS GEN. LAWS CH. 93A, § 11 CLAIM SHOULD BE DENIED

The Massachusetts Supreme Judicial Court has characterized Massachusetts Gen. Laws ch. 93A, § 11 as “a statute of broad impact which creates new substantive rights and provides new procedural devices for the enforcement of those rights” and has indicated that “recovery under the statute is not ‘limited by traditional tort and contract law requirements.’” *Auto Flat Car Crushers, Inc. v. Hanover Ins. Co.*, 469 Mass. 813, 821 (2014) (quoting *Slaney v. Westwood Auto, Inc.*, 366 Mass. 693 (1975)). “Chapter 93A creates a private cause of action against those who engage in “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” *Astellas Inst. for Regenerative Med. v. Imstem Biotech, Inc.*, No. 17-cv-406499, 2021 WL 406499, at *21 (D. Mass. Feb. 5, 2021) (Burroughs, J.) (citing Mass. Gen.

Laws ch. 93A, § 11). To be successful in bringing a claim under Chapter 93A, § 11, a plaintiff must plead and prove “(1) that the defendant engaged in an unfair or deceptive act or practice, as defined by [Mass. Gen. Laws ch. 93A, § 2], or the regulations promulgated thereunder; (2) a loss of money or property suffered as a result; and (3) a causal connection between the loss suffered and the defendant’s unfair or deceptive method, act, or practice.” *Auto Flat Car Crushers*, 469 Mass. at 823 (citations omitted). Plaintiffs must further plead and prove that defendants’ unfair or deceptive actions occurred primarily and substantially within the Commonwealth. *See Kuwaiti Danish Computer Co. v. Digital Equip. Corp.*, 438 Mass. 459, 470 (2003). Chapter 93A allegations involving fraud are subject to the heightened pleading requirements of Rule 9(b), which SRT meets here. *See Mulder v. Kohl’s Dept. Store, Inc.*, 865 F.3d 17, 22 (1st Cir. 2017).

Although Chapter 93A “does not define the term unfair, courts applying section 11 have developed a standard under which the objectionable conduct must attain a level of rascality that would raise an eyebrow of someone inured to the rough and tumble world of commerce.” *Indus. Gen. Corp. v. Sequoia Pac Sys. Corp.*, 44 F.3d 40, 43 (1st Cir. 1995) (internal citations and quotation marks omitted). “Further, a chapter 93A claimant must establish that the defendant’s actions fell within at least the penumbra of some common-law, statutory, or other established concept of unfairness, or were immoral, unethical, oppressive or unscrupulous, and resulted in substantial injury to competitors or other businesses.” *Id.* (internal citations and quotation marks omitted). “The crucial factors in an unfairness inquiry are the ***nature*** of the challenged conduct and on the ***purpose*** and ***effect*** of that conduct.” *Astellas*, 2021 WL 406499, at *21 (emphasis in original) (internal citations and quotation marks omitted). Said money or property damages suffered may include attorneys’ fees and costs, as well as “all foreseeable and consequential [monetary or property] damages arising out of the conduct which violates the statute.” *Auto Flat*

Car Crushers, 469 Mass. at 823 (internal citations and quotation marks omitted). Regarding causation, a plaintiff need not demonstrate actual reliance on the defendant's misrepresentations or deceptive acts so long as it can be proven that "a causal relationship existed between the misrepresentation and the injury." *Sebago*, 18 F. Supp.2d at 80.

Regarding the required connection to Massachusetts, "the Massachusetts Supreme Judicial Court does not use enumerated factors to analyze a primarily and substantially challenge, instead, preferring a fact-intensive approach in which the judge must consider whether the center of gravity of the circumstances that give rise to the claim is primarily and substantially within the Commonwealth." *Jofran Sales, Inc. v. Watkins & Shepard Trucking, Inc.*, 216 F. Supp.3d 206, 215–16 (D. Mass. 2016) (internal citations and quotation marks omitted). This "is not a determination that can be reduced to any precise formula." *Kuwaiti*, 438 Mass. at 472–73.

Applying these principles to the FAC, it is clear that SRT has adequately alleged a Chapter 93A claim at the pleadings stage. Specifically, SRT alleges that Defendants engaged in unfair and deceptive business practices including, *inter alia*, inducing SRT to enter into the Settlement Agreement and give up its viable claims in the Massachusetts Litigation. FAC, ¶¶ 247–60, 563. Other courts have required far less. *See, e.g. Rex Lumbar Co. v. Acton Block Co., Inc.*, 29 Mass. App. Ct. 510, 518–19 (1990) (sufficient evidence supported finding that prospective vendor violated Chapter 93A based on vendor's concealment). SRT also sufficiently alleges that Defendants' actions occurred primarily and substantially within the Commonwealth. Specifically, "[w]hile located in Massachusetts," Defendants knowingly misrepresented the facts and [their] intentions regarding the Settlement Agreement, misleading SRT into executing same and causing SRT to dismiss the Massachusetts Litigation." FAC, ¶ 56; *see e.g., Anthony's Pier Four, Inc. v. HBC Assocs.*, 411 Mass. 451, 474, 583 N.E.2d 806 (1991) ("Conduct in disregard of known

contractual arrangements and intended to secure benefits for the breaching party constitutes an unfair act or practice for c. 93A purposes”). Defendants also fraudulently spun-off 2seventy in Massachusetts and delayed SRT from providing its lentiviral vector gene therapy treatment to patients in Massachusetts, causing SRT substantial lost profits in Massachusetts. FAC, ¶¶ 565–67. Contrary to Defendants’ claim, ECF 57 at 43–44, the FAC alleges that SRT has been injured in Massachusetts given that many of Defendants’ alleged actions took place in Massachusetts, SRT lost its ability to provide its vector to patients in Massachusetts, and patients within Massachusetts are deprived of SRT’s gene therapy treatments. FAC, ¶¶ 5, 469–70, 475; *see Kuwaiti*, 438 Mass. at 472–73 (case cited by Defendants explaining that, in determining Chapter 93A claims, judges should, “after making findings of fact...determine whether the center of gravity of the circumstances that give rise to the claim” occurred in Massachusetts); *Jofran Sales, Inc.*, 216 F. Supp.3d at 216.

V. DEFENDANTS’ MOTION TO DISMISS THE MASS GEN. LAWS CH. 93, § 5 CLAIMS SHOULD BE DENIED

As discussed above, the FAC established multiple violations of the Sherman Act; Defendants did not challenge the elements of the Sherman Act violations; and Defendants “antitrust injury,” “release” and statute of limitations, and First Amendment arguments fail. Defendants’ argument the Massachusetts antitrust claims should be dismissed “for the same reasons” likewise fail. Defendants’ remaining arguments are also red herrings.

First, Defendants’ Massachusetts violations are subject to Massachusetts jurisdiction. The Massachusetts antitrust provision states that it does not apply to “any course of conduct, pattern of activity, or activities unless they occur and have their competitive impact primarily and predominantly within the commonwealth and at most, only incidentally outside New England.” Mass. Gen. Laws ch. 93, § 3. Defendants’ sole argument is that Beta Thalassemia is a worldwide

disease and therefore there is no special focus on Massachusetts. ECF 57 at 33–34. As an initial matter, Defendants do not challenge the FAC with respect to Sickle Cell Disease (SCD). FAC, ¶ 576.

The FAC expressly alleged “conduct violating Mass. Gen. Laws ch. 93, § 5 occurred and had its competitive impact primarily and predominantly within Massachusetts” and alleged the Massachusetts-based Defendants sought to protect the Massachusetts-based Zytteglo from competition by preventing SRT from launching in Massachusetts. FAC, ¶¶ 578–79. Indeed, bluebird (seller of Zytteglo) is a Massachusetts company, therefore making all of the monopolistic profits Massachusetts profits. FAC, ¶ 578. In this regard, Defendants cannot show “all of [their] allegedly anticompetitive conduct occurred and had [their] impact primarily and predominantly outside of Massachusetts.” *Tanol Distributors, Inc. v. Panasonic Co., Div. of Matsushita Elec. Corp. of America*, 1987 WL 13319 (D. Mass. July 2, 1987). Moreover, even a defendant that “is a large foreign corporation engaged primarily in interstate commerce is of no consequence under the terms of the Act.” *Id.* Rather, the “focus is on the location and effect of a defendant’s anticompetitive activities rather than on the overall nature of a defendant’s business.” *Id.* Indeed, “a defendant doing a substantial amount of business outside Massachusetts may be subject to the Act in appropriate circumstances” and “businesses engaged in interstate commerce enjoy no blanket exemption from the Act.” *Id.* Here, the anticompetitive activities of the Massachusetts-based Defendants predominantly take place in Massachusetts to secure Massachusetts-based bluebird as the sole supplier of treatments for Beta Thalassemia and Sickle Cell Disease. FAC, ¶¶ 573–79; *see also Tanol*, 1987 WL 13319 (D. Mass. July 2, 1987) (“Undoubtedly, some aspects of the allegedly wrongful activities occurred outside the commonwealth, but I find that a fair

construction of [plaintiff's] complaint suggests that the core of [defendant's] alleged anticompetitive conduct was within Massachusetts.”).

Not only are Defendants wrong on the law, their arguments lead to an absurd result: a Massachusetts resident could monopolize an entire industry in Massachusetts and evade Massachusetts oversight by succeeding in broader monopolization. That is not the law, as discussed above. And, in any event, the Defendants' monopoly formed and is seated in Massachusetts. FAC, ¶¶ 573–79. At minimum, fact issues as to Defendants' conduct in Massachusetts preclude judgment.

While moot in light of the above, Defendants also misapply the burdens. Under Section 3, the burden is on the person asserting lack of jurisdiction to prove lack of jurisdiction except for “any course of conduct, pattern of activity, or activities of any person of whose gross revenue at least ten per cent is derived from transactions involving interstate commerce outside of New England.” Mass. Gen. Laws ch. 93, § 3. While Defendants are engaged in interstate commerce, 100% of Defendants’ gross revenues from antitrust violations occur in Massachusetts as Massachusetts Defendant bluebird is the sole supplier of Zynteglo. FAC, ¶¶ 573–79.

Moreover, Defendants’ Massachusetts violations are not exempted under Massachusetts law. With respect to Massachusetts’ antitrust law, “[n]o provision of this Act shall apply to . . . [a]ny activities which are subject to regulation or supervision by state or federal agencies.” Mass. Gen. Laws ch. 93, § 7. This is a narrow statute: “[i]n the absence of an explicit federal exemption, an activity only escapes state antitrust scrutiny if it is mandated by state law or regulation.” *Am. Tel. & Tel. Co. v. IMP Capital Co.*, 888 F. Supp. 221, 244 (D. Mass. 1995). According to Defendants, § 7 excludes the antitrust action because “[t]he FDA, a federal agency, governs the drug approval process and dictates the timing of any commercial launch.” ECF 57 at 34. But

nowhere does the FAC allege FDA action is the anticompetitive action, making Defendants' entire argument inapposite. Rather, the FAC alleged numerous acts by Defendants to delay SRT and monopolize the market. The FDA did not sabotage SRT, the FDA did not use SRT's proprietary information to leapfrog SRT, and the FDA is not conspiring to keep SRT off the market to maintain Defendants' supracompetitive prices. Indeed, Defendants have not shown the FDA has any "regulation or supervision" authority with respect to these antitrust violations. At best, there is a fact dispute over whether Defendants anticompetitive conduct is subject to regulation or supervision by the FDA.

Defendants' reliance on *American Transport* is misplaced. Unlike *American Transport*, the issue here is Defendants' efforts to delay SRT from coming on the market so that Defendants can charge supracompetitive prices. In *American Transport*, the anticompetitive activity involved *defendants'* failure to submit its own data to a regulator, causing the regulator to set lower rates for the industry, which in turn injured plaintiff by limiting what it could legally charge. *Am. Transp. Ins. Co., Inc. v. Balboa Ins. Co.*, No. CIV. 88-1834-MC, 1989 WL 90425, at *1 (D. Mass. Aug. 2, 1989). In rejecting the claim, the court noted the regulator's data collection and rate setting practices were subject to regulation. *Id.* The mere fact the market is regulated in other ways does not exempt Defendants' unchallenged violations of antitrust law. *Commonwealth v. Mass. Crinc*, 466 NE 2d 792, 91 (1984) (rejecting exemption from antitrust violations for thwarting competitors, noting Defendants actions were not required by statute or regulation and therefore not exempt).

VI. DEFENDANTS' CATCHALL ARGUMENTS FAIL

Defendants' catchall arguments fail. ECF 57 at 45–46. Here, the only allegations Defendants refer to are fraudulent inducement and RICO, which are addressed above. Moreover, Defendants arguments consist of bare denials divorced from the FAC's actual allegations. For example, Defendants argue Leschly "left bluebird in 2021 and is not alleged to have had any role

in any post-settlement conduct upon which SRT relies.” ECF 57 at 46. This ignores the FAC, which contains pervasive allegations directed at Leschly after execution of the Settlement Agreement. *See, e.g.*, FAC, ¶ 289 (“Leschly... **currently serves** as a Board member of bluebird.” (emphasis added)), 28 (“After execution of the Settlement Agreement, **led by...** **Leschly**, the Leschly Enterprise engaged (and continues to do so) in unlawful activities...” (emphasis added)). Defendants make similar bare denials about Finer, Reilly, and 2seventy while ignoring the FAC’s allegations of on ongoing enterprise. For example, Defendants claim 2seventy “is an oncology company . . . and thus does not plausibly compete with SRT.” ECF 57 at 46. Yet the FAC explains how 2seventy was formed by transferring assets from bluebird in an effort to protect Defendants and further the misconduct. FAC, ¶¶ 261–99, 345–58. In short, Defendants’ catchall paragraph contradicts the FAC and their bare denials represent—at best—fact disputes inappropriate for dismissal. *See, e.g.*, *US ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F. 3d 377, 383–84 (1st Cir. 2011) (Rule 12(b)(6) requires “accepting as true all well-pleaded facts, analyzing those facts in the light most hospitable to the plaintiff’s theory, and drawing all reasonable inferences for the plaintiff.”). In addition, Defendants claim they “reserve the right to join in any additional arguments” Defendant Thompson may raise in his October 23, 2023 motion.” ECF 57 at 46 n. 8. That is improper. Defendants were obligated to file their Motion “by no later than September 18, 2023.” ECF 46 (denying Defendants’ Motion for an Additional Extension of Time); Fed. R. Civ. P. 12. Indeed, Defendants should not be permitted to coordinate with Defendant Thompson to circumvent both the schedule and page limits upon which the court ruled. ECF 46.

CONCLUSION

For the foregoing reasons, Defendants’ Motion should be denied in its entirety.

Dated: October 12, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Erika Page, Esq., do hereby certify that on this date, I served a copy of the foregoing via ECF.

/s/ Erika M. Page
Erika Page, Esq.

Dated: October 12 , 2023